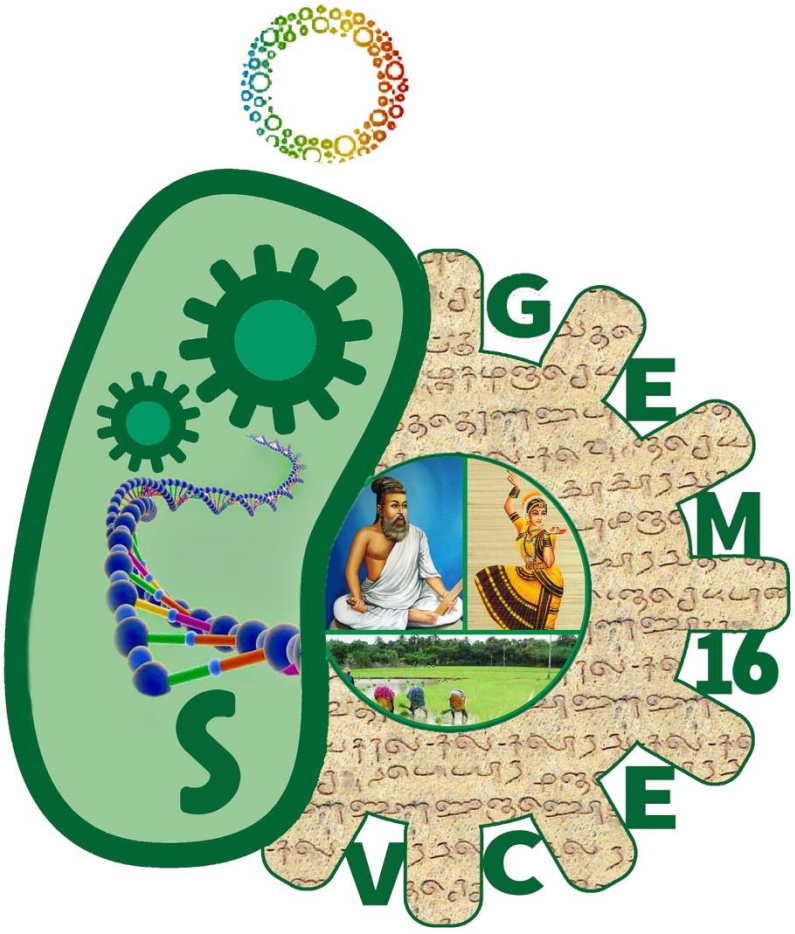
A REPORT ANALYSING AND COMPARING THE DIFFERENT REGULATORY MECHANISMS OF GMOs AROUND THE WORLD

- SVCE_CHENNAI 2016



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1. Introduction

After team SVCE_CHENNAI zeroed in on working on prolonging the shelf life of milk, we realized it was important for us to assess the kind of impact our product would have on the society. Hence, we conducted rural and urban surveys to assess the same(exact statistics can be found in our wiki). Both surveys confirmed that there was a need for a solution on a consumer level to prolong the shelf life of milk ,especially in the lack of refrigeration. And given that 400 million people(1 in 3 persons) in India do not have access to regular supply of electricity, it is safe to infer that a significant portion of the Indian population doesn't have access to refrigeration. Hence we concluded that our system would have a significant impact on the dynamics of milk spoilage.

To understand what it would take us to commercialize and get our product into the market, we interacted with several milk industries and research scholars. While the responses of each one of them varied, there were two points/concerns that were unanimously expressed: a)The cost of our system- they said how the usage of a dialysis membrane would make our system economically unviable and that we have to find a suitable alternative ,b)they told us how its almost impossible to introduce Genetically Modified Organisms(GMOs) into the Indian market, because of the strict regulatory laws. Hence we decided to understand the regulatory mechanism to release GMOs in India. We understood that there is a complex chain of regulatory framework in India for the purpose of biosafety when it comes to releasing GMOs. We decided to prepare a report briefing the regulatory mechanism of GMOs, so that future iGEM teams from India would have a good starting point when it came to understanding the intricacies involved in the regulatory mechanism.

While our projects primary focus is on the Indian subcontinent, it is no secret that other countries situated in tropical zones where there is high humidity leading to the spoilage of milk would benefit from our project. We looked into how other countries compared with the regulatory mechanisms in place in India, and much to our surprise found that there was substantial variation in the regulation of GMOs around the world. This is even more surprising given the fact that countries have similar laws in place when it comes to conducting research and studying GMOs, but there is variation when it comes to their regulation. This led us to not limiting our report to India, but rather extend it to the entire iGEM community in general. This report also focuses on some of the major controversies surrounding GMOs in various countries in the past.

http://2016.igem.org/Team:SVCE_CHENNAI/AttributionsWhile it is noteworthy that previous iGEM teams have focused on understanding public perception of GMOs(iGEM teams- HokkaidoU_Japan 2015,NTU Singapore 2015) some others have focused on the general status of GMOs in different countries(iGEM teams-Wageningen UR 2014, Team:Zamorano 2014) and some have focused on regulating GMOs in their country only(iGEM teams-NYMU-2015, BCCS-Bristol-2010).We felt that there was a need for a comprehensive report focusing on the exact regulatory process in different countries, and hearing the advantages and disadvantages of each system from experts and law makers around
the world and also consider the possibility of all nations adopting a uniform stance under an intergovernmental organization such as the United Nations.

2. Overview

As a general rule regulatory politics in the United States of America tend to be more contentious, confrontational and adversarial than in Europe. Countries such as the United States and Canada use substantial equivalence as the starting point when assessing safety. Other countries such as those in the European Union have precautionary approach towards the field of genetically modified organisms (GMOs) and evaluate their safety on a case-by-case basis. In India the DBT, department of science and technology and ministry of environment and forest (MOef) is the two main regulatory body . In China, restrictions on GMOs are primarily provided by the agricultural GMO regulations enacted by the State Council in 2001 and relevant administrative rules. The agricultural GMO regulations regulate not only crops, but also animals, microorganisms, and products derived from these sources. Many countries allow the import of GM food with authorization, but either do not allow its cultivation (Russia, Norway, Israel) or have provisions for cultivation, but no GM products are yet produced (Japan, South Korea).

The EU has moved away from the initial World Trade Organization (WTO) and Organization for Economic Cooperation and Development (OECD) consensus and shifted toward strict safety assessment and mandatory labeling. In Canada and the USA labeling of GM food is voluntary.

a. Substantial Equivalence

"Substantial equivalence embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety (i.e., the food or food component can be concluded to be as safe as the conventional food or food component)" (Joint United Nations Food and Agricultural Organisation(FAO)/World Health Organisation(WHO) Biotechnology and Food Safety Report, 1996, p. 4).

"Establishment of substantial equivalence is not a safety assessment in itself, but a dynamic, analytical exercise in the assessment of the safety of a new food relative to an existing food. The comparison may be a simple task or be very lengthy depending upon the amount available knowledge and the nature of the food or food component under consideration. The reference characteristics for substantial equivalence comparisons need to be flexible and will change over time in accordance with the changing needs of processors and consumers and with experience." (Joint FAO/VMO Biotechnology and Food Safety Report, 1996, pp. 4 and 5).

In other words, substantial equivalence holds that the safety of a new food, particularly one that has been genetically modified, may be assessed by comparing it with a similar traditional food that has proven safe in normal use over time.Substantial equivalence is the underlying principle in GM food safety assessment for a number of national and international agencies, including the Canadian Food Inspection Agency (CFIA), Japan's Ministry of Health, Labor and Welfare (MHLW), the US Food and Drug Administration (FDA), the FAO and WHO.

In 1999, Andrew Chesson of the Rowett Research Institute warned that substantial equivalence testing "could be flawed in some cases" and that current safety tests could allow harmful substances to enter the human food supply. The same year Millstone, Brunner and Mayer argued that the standard was a pseudo-scientific product of politics and lobbying that was created to reassure consumers and aid biotechnology companies to reduce the time and cost of safety testing. They suggested that GM foods need to have extensive biological, toxicological and immunological tests and that substantial equivalence should be abandoned.

Kuiper examined this process further in 2002, finding that substantial equivalence does not measure absolute risks, but instead identifies differences between new and existing products. He claimed that characterizing differences properly is a starting point for a safety assessment and "the concept of substantial equivalence is an adequate tool in order to identify safety issues related to genetically modified products that have a traditional counterpart". Kuiper noted practical difficulties in applying this standard, including the fact that traditional foods contain many toxic or carcinogenic chemicals and that existing diets were never proven to be safe. This lack of knowledge of conventional food means that modified foods may differ in anti-nutrients and natural toxins that have never been identified in the original plant, possibly allowing harmful changes to be missed. In turn, positive modifications may also be missed. For example, corn damaged by insects often contains high levels of fumonisins, carcinogenic toxins made by fungi that travel on insects' backs and that grow in the wounds of damaged corn. Studies show that most Bt corn has lower levels of fumonisins than conventional insect-damaged corn.

b. Labeling

In 2014, 64 countries required labeling of all GM foods. These include the European Union, Japan, Australia, New Zealand, Russia, China and India .As of March 2015, Israel was in the process of issuing regulations for labeling of food with ingredients from GMOs. Major GM food crop exporters like the United States (until 2018), Argentina, and Canada have adopted voluntary labeling approaches; China and Brazil have major GM (largely non-food) crops and have adopted mandatory labeling.

The American Public Health Association, the British Medical Association and the Public Health Association of Australia support mandatory labeling. The European Commission argued that mandatory labeling and traceability are needed to allow for informed choice, avoid potential misleading of consumers and facilitate the withdrawal of products if adverse effects on health or the environment are discovered.[1] A 2007 study on the effect of labeling laws found that once labeling went into effect, few products continued to contain GM ingredients. The study also found that costs were higher in food-exporting than in food-importing countries.

The American Medical Association (AMA) and the American Association for the advancement of Science have opposed mandatory labeling absent scientific evidence of harm. The AMA said that even voluntary labeling is misleading unless accompanied by focused consumer education. The AAAS stated that mandatory labeling "can only serve to mislead and falsely alarm consumers".

3. Regulation

In this report along with the system in India we also decided to focus on the regulatory mechanisms of those countries having maximum representation in iGEM 2016 i.e., USA(77), China(63), the countries in the European Union(U.K(22), Germany(13), France(10), Netherlands(5)), Canada(17), Taiwan(9), Mexico(8) and Japan(8).

a. India

The top biotech regulator in India is Genetic Engineering Appraisal Committee (GEAC). The committee functions as a statutory body under the Environment Protection Act 1986 of the Ministry of Environment & Forests (MoEF). It was earlier known as Genetic Engineering Approval Committee. Under the EPA 1986 "Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989", GEAC is responsible for granting permits to conduct experimental and large-scale open field trials and also grant approval for commercial release of biotech crops.

The Rules of 1989 also define five competent authorities i.e. the Institutional Biosafety Committees (IBSC), Review Committee of Genetic Manipulation (RCGM), Genetic Engineering Approval Committee (GEAC), State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC) for handling of various aspects of the rules.

3.1.1 Genetic Engineering Appraisal Committee(GEAC):

a) This Committee functions as a Statutory Body under the Ministry of Environment & Forests for approval of activities involving large-scale use of hazardous living microorganisms and recombinants in research and industrial production from the environmental angle as per the provisions of rules 1989.
b) This Committee is also responsible for approval of proposal relating to release of genetically engineered organisms and products into the environment including experimental field trials as per the provisions of Rules, 1989.
c) This Committee is also responsible for approval of proposals involving the use of living modified organism falling in the risk category Ill and above in the manufacture/import of recombinant pharmaceutical products or where the end product of the recombinant pharmaceutical products per se is a living modified organism.
d) This Committee can co-opt other members/experts to the GEAC in accordance with the provisions of Section 4, paragraph 3 of the Rules, 1989 as necessary.
e) This Committee may also appoint subgroups/sub-committees/expert committee to undertake specific activities related to compliance of biosafety.
f) One third members of the GEAC will constitute the quorum for convening the meeting.

g) The members of the GEAC will be required to sign a 'Statement of Declaration of Independence' and 'Statement of Confidentiality' (as per enclosed proforma).

h) This Committee shall function for a period of three year from the date of issue of this notification.

i) With the approval of the Chairman GEAC, if required, representative of other Ministries and other experts may be invited as 'Special Invitees' to participate in the meeting of the GEAC depending on the issues to be discussed.

It is also compulsory to label GMOs in India.

b. United States of America

GMOs are regulated in the United States under the Coordinated Framework for Regulation of Biotechnology, published in 1986, pursuant to previously existing statutory authority regulating conventional products, with a focus on the nature of the products rather than the process in which they are produced.

The United States does not have any federal legislation that is specific to GMOs. Rather, GMOs are regulated pursuant to health, safety, and environmental legislation governing conventional products. The US approach to regulating GMOs is premised on the assumption that regulation should focus on the nature of the products, rather than the process in which they were produced.

The three main agencies involved in regulating GMOs are the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS),the FDA, and the Environmental Protection Agency (EPA).

3.2.1 Agriculture's Animal and Plant Health Inspection Service (APHIS):

APHIS regulates the planting, importation, or transportation of GM plants pursuant to

its authority under the Plant Protection Act (PPA),which authorizes the Secretary of Agriculture to "prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product .

APHIS grants authorization to use GM plants in three ways: through a notification process, a permitting process, or a determination of nonregulated status.

a) Notification Procedure

The notification procedure is available to plants that are not classified as noxious weeds, or weeds in the release area, if certain criteria and performance standards are met. The criteria include that the plant must be a species that APHIS has determined may be safely introduced; the genetic material must be stably integrated; the expression of the genetic material must not result in plant disease; etc. The performance standards govern shipment, storage, planting, and testing, and are intended to prevent the plant from being released from containment. When the applicant sends a notification to APHIS, APHIS will respond within a prescribed time with an acknowledgement or a denial.If the notification is denied, the applicant may apply for a permit.

b) Permit Procedure

The permit procedure requires an applicant to submit information concerning, among other things, the donor organism, the recipient organism, the composition of the regulated article; the expression of altered genetic material in the regulated article and the molecular biology of the system used to produce the article; the locality where the donor and recipient organisms and the regulated article were developed; the purpose of the regulated article; the quantity to be introduced; processes to prevent release; the intended destination, use, and distribution; and the final disposition of the regulated article. If APHIS grants the permit, it is subject to conditions designed to ensure both that the regulated article remains contained and that APHIS can maintain regulatory oversight. Failure to comply with the conditions can result in withdrawal of the permit.

c) Determination of Non-regulated Status

GM plants that have been tested and have been shown not to pose a risk may be eligible for a determination of non-regulated status. A petition for determination of non-regulated status must include detailed biological information on the regulated article and the recipient organism, published and unpublished scientific studies, data from field tests, and other information designed to assist APHIS in determining whether the plant constitutes a pest. Upon receipt of a petition, APHIS publishes a notice in the Federal Register and allows sixty days for public comment. APHIS has 180 days to approve in whole or part or deny the petition.

3.2.2 Food and Drug Administration

a)The FDA regulates the safety of all human and animal food products in the US (other than meat, poultry, and eggs), as well as drugs and biological products.

b)In a 1992 policy statement, the FDA reaffirmed that in most cases it would treat foods derived from GMOs like those derived from conventionally bred plants, and that most foods derived from GM plants would be presumptively GRAS. However, with respect to a GMO product "that differs significantly in structure, function, or composition from substances found currently in food," premarket approval of the substance as a food additive would be required.

c)The FDA encourages developers of new plant varieties intended for food use, including GMOs, to engage in a consultation procedure with the FDA, in order "to ensure that human food and animal feed safety issues or other regulatory issues (e.g. labeling) are resolved prior to commercial distribution." The consultation procedure is meant to enable the FDA to determine if regulatory action is needed with respect to food derived from the new variety such as "significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food of an unapproved food additive."

d) The FDA also regulates medical products classified as "biological products," which includes vaccines, serums, blood products, and the like, under relevant provisions of the Public Health Service Act (PHSA).[59] Biological products, whether involving genetic modification or not, must be licensed by the FDA before they can be introduced.

3.2.3 Environmental Protection Agency:

The EPA regulates pesticides and microorganisms developed through genetic engineering.

a) The EPA regulates the manufacture, sale and use of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Pursuant to its authority under FIFRA, the EPA regulates plants that are genetically modified to produce substances intended to control pests as to both their environmental safety and their safety in food, termed plant-incorporated protectants (PIPs). The standard registration procedures for pesticides apply to PIPs, unless they are made exempt by regulation. PIPs are exempt from FIFRA registration if the PIP is used in a crop used in food and its residues are exempt from regulation under the FFDCA,if the PIP is an inert ingredient listed as exempt by the EPA,or if the PIP is from a plant that is sexually compatible with the recipient plant.

b) The EPA also has authority to regulate GMOs under the Toxic Substances Control Act (TSCA). The TSCA authorizes the EPA to regulate chemical substances that may present an unreasonable risk of injury to health or the environment. Manufacturers of covered substances must submit a pre-manufacture notification to the EPA. The EPA has determined that GMO microorganisms are chemical substances subject to regulation under the TSCA. The EPA has established regulations specifically for microorganisms that require submission of a Microbial Commercial Activity Notice (MCAN) before they are used for commercial purposes. The Notice must include information describing the microorganism's characteristics and genetic construction; byproducts of its manufacture, use, and disposal; health and environmental effects data; and other information.

   There is no law in the US requiring that GMO foods or foods with GMO ingredients be labeled to so indicate. Proposed federal legislation, the Genetically Engineered Food Right-to-Know Act,which would mandate labeling of any GMO food or food with a genetically modified ingredient, has been introduced in the last several Congresses, but has never advanced beyond the committee stage in either chamber. The FDA has regulatory authority to prevent false and misleading labeling of foods and drugs. With respect to genetically engineered foods, the FDA has stated in policy documents that if a GM food product is not materially different from its traditional counterpart, there is no need to label or change the name of the product, but name changes are appropriate when a food from a GM plant is so different from its traditional counterpart that the usual name no longer adequately describes the new food, or if there is a safety issue to which consumers should be alerted, such as the presence of allergens.

3.3 China

In China, restrictions on GMOs are primarily provided by the agricultural GMO regulations enacted by the State Council in 2001 and relevant administrative rules. The agricultural GMO regulations regulate not only crops, but also animals, microorganisms, and products derived from these sources.

The testing, production, and marketing of GMOs in China are subject to government approval. Foreign companies that export GMOs to the PRC, including GMOs as raw materials, must apply to the Ministry of Agriculture and obtain GMO Safety Certificates.

China has not passed a national law specifically regulating GMOs. Restrictions are primarily on agricultural GMOs, which are provided by the GMO Regulations enacted by the State Council in 2001 and the administrative rules implementing the GMO Regulations. The GMO Regulations are designed to regulate not only crops, but also animals, microorganisms, and their products. Agricultural GMO research, testing, production, processing, business operations, and import/export activities within the PRC's territory are subject to the GMO Regulations.

The MOA and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) have issued the following administrative rules implementing the GMO Regulations, which regulate, respectively, safety evaluations, processing, labeling, import, and entry and exit inspections and quarantine:

- Administrative Measures for Safety Evaluations of Agricultural GMOs (Safety Evaluation Measures).
- Measures for Examination and Approval of the Processing of Agricultural GMOs
- Administrative Measures for Labeling Agricultural GMO Marks (Labeling Measures)
- Administrative Measures for Safety Control for Importing Agricultural GMO Products
- Administrative Measures on the Entry and Exit Agricultural GMO Products Inspection and Quarantine.

In addition, the Ministry of Forestry has issued a separate document regulating gene-altered engineering of trees in forests (Forestry Measures).

The Ministry of Health (MOH) issued the Administrative Measures for Genetically Modified Food Hygiene in 2002, but those measures were abolished in 2007. GMO foodstuffs are now subject to the Agricultural GMO Safety Regulations. There is no separate legislation specifically regulating GMO foodstuffs today.

Apart from the aforementioned legislation, the PRC Law on Seeds,PRC Law on Fisheries,PRC Law on the Environment,and the Administrative Measures for Safety Control over Genetic Engineering contain provisions relating to GMOs.

Zhangye City in China's Gansu Province recently issued a ban on growing, selling, or using any GM seeds. This is the first local ban on GM seeds in China. In a document released on October 25, 2013, the city government ordered that no organizations or companies may grow, trade, or use any GM seeds in the area.

GMO products on the GMO list published by the state must be clearly labeled when sold within the PRC territory; unlabeled products may not be sold.[51] The label should indicate the name of the GM materials and, if there are special restrictions on where it may be sold, the area in which it will be sold.

3.4 Canada

Canada regulates products derived from biotechnology processes as part of its existing regulatory framework for "novel products." The focus is on the traits expressed in the products and not on the method used to introduce those traits. The Canadian Food Inspection Agency (CFIA) is responsible for regulating GM plants and approving GM feed for animals. Health Canada is mandated to assess the safety

of foods for human consumption, including GMOs in foodstuff, and for authorizing them to be sold in Canada. Advertising or labeling the presence of GMOs in particular food is voluntary unless there is a health or safety concern.

Health Canada and the CFIA are both mandated to evaluate the safety and nutritional value of genetically modified foods released in Canada.

Genetically modified or genetically engineered (GE) foods are primarily regulated by the *Food and Drugs Act* and its subordinate regulations. Health Canada is responsible, under the above legal framework:

> for provisions related to public health, food safety and nutrition. Through science-based regulation, guidelines and public health policy, as well as health risk assessments concerning chemical, physical and microbiological contaminants, toxicants and allergens in the food supply, Health Canada works to protect the health and safety of Canadians. Health Canada also conducts pre-market evaluations to assess the safety and nutritional adequacy of novel foods proposed for sale in Canada, including foods derived from biotechnology.

Under Canada's regulations, GE and GM foods are classified as one class of "novel foods." Health Canada "regulates the sale of novel foods in Canada through a pre-market notification requirement which is specified under Division 28 of Part B of the *Food and Drugs Regulations."*
The CFIA "is responsible for regulating the environmental release of a plant with a novel trait (PNTs)." This mandate is authorized through the following laws and regulations: the Plant Protection Act, Plant Protection Regulations, the Seeds Act and Seed Regulations .

Advertising or labeling of products containing GMOs or derived through GE processes is largely voluntary in Canada. There have been three major public consultation processes since 1993 in Canada on the labeling of novel foods derived from genetic engineering. Therefore, in Canada labeling is required "if there is a health or safety issue with the food which might be mitigated through labeling" (e.g., if the "nutritional value or composition has been changed or if an allergen is present"). This rule applies to all novel foods, whether GM or not.

3.5 European Union

The European Union has in place a comprehensive and strict legal regime on GMOs, food and feed made from GMOs, and food/feed consisting or containing GMOs. The EU's legislation and policy on GMOs, based on the precautionary principle enshrined in EU and international legislation, is designed to prevent any adverse effects on the environment and the health and safety of humans and animals, and it reflects concerns expressed by skeptical consumers, farmers, and environmentalists.

GMOs and food or feed made from GMOs can be marketed in or imported into the EU, provided that they are authorized after passing strict evaluation and safety assessment requirements that are imposed on a case-by-case basis. Authorizations are granted for a ten-year period by the European Commission through a centralized procedure, as provided for in Regulation No. 1829/2003, or by national competent authorities under Directive 2001/18/EC, which regulates the intentional release of GMOs into the environment. At the

EU level, the European Food and Safety Authority (EFSA) conducts the required risk assessments. GMOs, or food and feed consisting of or containing GMOs, are assigned a unique identifier and are labeled as such to ensure traceability and enable consumers to make informed choices.

While marketing and importing GMOs and food and feed produced with GMOs are regulated at the EU level, the cultivation of GMOs is an area left to the EU Members. EU Members have the right to prohibit or restrict the sale or cultivation of approved GMOs based on adverse effects on health and the environment. A pending Commission proposal, as amended by the European Parliament, will give EU Members more flexibility to invoke socioeconomic grounds and impacts on local or regional environments when imposing such measures.

3.5.1 United Kingdom

The growth and sale of GMOs are permitted in England and Wales, subject to an intensive authorization process that occurs primarily at the European Union level. Most legislation in England and Wales that applies to GMOs is implementing legislation for EU law.

Legislation in England and Wales governing GMOs serves to implement EU law. The Environmental Protection Act 1990 is the primary piece of legislation that addresses GMOs and provides the Secretary of State with the authority and responsibility to control the deliberate release of GMOs in England.

The laws that govern the environment and the use of GMOs are primarily based on EU law. The main piece of national legislation that regulates the environment is the Environmental Protection Act, which provides the Secretary of State with the power and responsibility to control the deliberate release of GMOs in England. At the EU level, the main EU directive that regulates the release of GMOs across Member States is Directive 2001/18.This was implemented in the national law of England through the Genetically Modified (Deliberate Release) Regulations 2002.

The Department for Environment, Food and Rural Affairs (DEFRA) is the lead government department in England for protecting the environment. How it conducts these responsibilities with regard to GMOs is detailed in Part V, below.

The laws that govern the use and labeling of GMOs in food are extensive, and are again primarily based upon EU law. The EU Regulations that govern the use of GMOs in food products across Member States are Regulations 1829/2003 and 1830/2003.These are implemented in England by the Genetically Modified Food (England) Regulations 2004, the Genetically Modified Animal Feed (England) Regulations, and the Genetically Modified Organisms (Traceability and Labelling) (England) Regulation.

Foods containing or consisting of GMOs must comply with EU regulations that require any approved GM products to be clearly labeled. This requirement includes foods derived from GM crops, even if they do not have a detectable GM content. The labeling rules are extensive and require the disclosure of the presence of any GM material in the final product.

3.5.2 Germany

Germany discourages the cultivation of genetically modified (GM) crops to the extent possible within the already stringent European Union (EU) legislation on genetically modified organisms (GMOs). Germany imposes strict liability for accidental contamination with GMOs, and has tough and methodically enforced controls over the release of GMOs. In 2009 Germany banned MON810 maize from cultivation for agricultural purposes, even though the EU has approved it for release into the environment. The only other GM plant that the EU has approved for release, the Amphora potato, is currently not being grown as a crop in Germany. Since 2013 the experimental planting of GM plants has also been abandoned owing to persistent vandalism.

In Germany the research, production, marketing, and release of GM plants are governed by the Genetic Engineering Act. The Act deals with GMOs in both plants and animals but does not deal with food or feed containing GMOs. The latter are governed by directly applicable EU regulations, primarily Regulations 1829/2003 on GMOs in food or feed and 1830/2003 on the traceability and labeling of GMOs and foods containing them, with German legislation limited to the implementation of the EU rules. Nor does the German Genetic Engineering Act deal with GMOs in pharmaceutical products. The Act on Pharmaceutical Drugs and various best-practice guidelines for producing pharmaceutical drugs apply to these.

The purposes of the Genetic Engineering Act are threefold. First, the Act aims to protect the environment and human and animal health from risks emanating from GMOs. Second, the Act aims to guarantee that genetically modified, conventionally produced, and organically grown products, particularly food and feed, can be grown, produced, and marketed in coexistence with each other. Third, the Act creates the legal framework for research on and the development and economic use of GMOs.

3.5.3 France

The production and sale of certain GMOs are legal in France, but are subject to very restrictive rules. French legislation regarding GMOs falls within the broader framework of European regulation, but France has supplementary national rules that provide additional restrictions. These rules are particularly focused on the potential release of GMOs in the environment, and on labeling requirements for GM products. French legislation also requires that the location of GM crops be public information, and establishes strict liability rules regarding the possible release of GM crops into non-GM fields.

One of the key elements of French legislation on GMOs is the establishment of a special high council called the Haut Conseil des biotechnologies (High Council for Biotechnologies). This high council is comprised of a number of experts and representatives from the political sphere, from community organizations, and from relevant advocacy and professional groups. It is divided into a scientific committee, and an economic, ethical, and social committee.As will be seen below, many French legislative provisions require the governmental authorities to seek advice from the Haut Conseil des biotechnologies on the topic of GMOs.

At the local level, many mayors and town councils have tried to issue regulations prohibiting the cultivation of genetically modified organisms within their jurisdictions, but such measures have been systematically challenged by the prefects and struck down by administrative courts.

3.5.4 Netherlands

Although the Netherlands was the first European Union Member State to have legal coexistence guidelines on genetically engineered crops, commercial production of genetically modified crops has not yet taken place there, and there are no GE livestock. While the government and the agriculture sector take a pragmatic approach toward the import and use of GM products, public opinion is divided as to whether GM foods pose health risks, and the complex regulatory environment and effective pressure from environmental groups have worked to hamper the commercial manufacture of GMOs.

The Netherlands Food and Consumer Product Safety Authority and the Institute of Food Safety are responsible for determining the safety of GMO food and feed, respectively. Labeling of pre-packaged food products for sale in the Netherlands requires conformity with the Food Labeling (Commodities Act) Decree and the relevant EU Regulation on food and feed. Contained-use license holders must ensure, if making GMOs available to another party, that the GMO packaging label or the document accompanying the GMOs clearly indicates the presence of GMOs.

The basic purpose of current Dutch legislation on GMOs is to implement European Union directives on the subject, which seek to balance the promotion of scientific progress with protection of the environment and consumer safety. This is mainly accomplished in the GMO Decree. The overarching national law on which the GMO Decree is based is the Environmentally Hazardous Substances Act. In addition to the GMO Decree, key items of legislation implementing the EU law in the Netherlands are the Regulation on GMOs, the Environmental Management Act, the Food and Commodities Act, and the Decree on Novel Foods.

At the local level, cities and provinces have taken action against GMOs. For example, on January 26, 2011, Friesland Province became the first GMO-free region in the Netherlands, and in July of that year the Community Council of Nijmegen declared the city to be GMO-free.

3.6 Japan

Although it is legal to plant genetically modified crops in Japan if certain procedures are followed, no commercial planting of GM crops (aside from ornamental flowers) is occurring in Japan at this time, mainly because the general public is skeptical about the safety of GM crops. Nevertheless, Japan is one of largest importers of GMO foods, though labeling is required if GM crops are used in food in certain cases.

Japan enacted the Cartagena Act in 2003 to implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Act classifies genetically modified organisms according to two types

of uses: use with containment measures and use in open space. Both uses are regulated by the Act, but the latter use is the more regulated of the two.

The Cartagena Act implements the Cartagena Protocol. Domestic food laws regulate the safety of GM food crops . Additionally, the Pharmaceutical Affairs Act regulates the assessment of pharmaceuticals that use GMOs.

GMOs are defined in the laws and regulations in slightly different ways, depending on the purpose of the laws and regulations. The definition of a GMO under the Cartagena Act is as follows:

- In this Act, "living modified organism" shall mean an organism that possesses nucleic acid, or a replicated product thereof, obtained through use of the any of the following technologies.
- Those technologies, as stipulated by the ordinance of the competent ministries, for the processing of nucleic acid extracellularly.
- Those technologies, as stipulated by the ordinance of the competent ministries, for fusing of the cells of organisms belonging to different taxonomical families.

The Act obligates the government to adopt general measures (known as "Basic Matters") that are designed to prevent adverse effects caused by the use of GMOs and ensure their proper use. The government established these Basic Matters in the form of an ordinance in 2003.
In addition to national legislation, there are local ordinances that regulate GM crops. Eleven prefectures and three municipalities have enacted ordinances or issued guidelines for restrictions on the planting of genetically modified crops within their jurisdictions that go beyond the restrictions established in the Cartagena Act.Local residents' groups concerned about the safety of GM crops have demanded that such ordinances be passed by their local governments.
Although it is legal to grow government-approved GM crops commercially so long as procedures under the Act and local ordinances are followed, no GM crops (aside from ornamental flowers) are commercially grown in Japan at this time.

As a part of the legal safety assessment system under the Food Sanitation Law, there is a labeling system for GM foods and two corresponding laws that include provisions on labeling: the Japanese Agricultural Standards Law (JAS Law) and the Food Sanitation Law.The two labeling systems are almost the same, and only one label is required.

3.7 Mexico

Mexico's Law on Biosecurity of GMOs is the main federal statute pertaining to these organisms. It provides rules on research concerning, and the release, commercialization, exportation, and importation of, GMOs, and is aimed at preventing, avoiding, or reducing the risks that these activities may cause to human health, the environment, biological diversity, or the health of plants and animals. It also provides that the policy pertaining to biosecurity of GMOs is to ensure that these organisms are released, commercialized, exported,

and imported with an adequate level of safety. Approval of GMOs for human consumption requires a study of the possible risks that consumption of the GMO may present for human health. Prior to their release, GMOs must be subject to risk studies and successful approval of experimental releases. Authorization for release may be denied if it is determined that the risks posed by a GMO may negatively affect human health; biological diversity; or the health of animal, plants, or water organisms by causing them grave or irreversible harm. The GMO Law provides that violations of its provisions or its regulations are punishable with civil penalties.

Labels of genetically modified seeds or plants for agricultural production must indicate that these products are GMOs, and must describe their genetically acquired characteristics, special requirements for their cultivation, and changes in reproductive capabilities.

4 Cartagena Protocol on Biosafety(CPB)

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003.

Article 1 of the protocol unequivocally states the objective of the protocol," *the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements. "*

The Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a precautionary approachand reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a biosafety Clearing-House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol. It established an open-ended ad hoc Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) with a mandate to undertake the preparations necessary for the first meeting of the Parties to the Protocol.

There protocol has 170 signatories ,while all of the above mentioned nations in this report are signatories, the United States of America isn't. The United States cannot become a Party to the CPB because they are not a Party to the parent Convention on Biological Diversity .The US believe that while the protocol has a comprehensive and safe approach to protecting biodiversity, it may impede the trade of commodities.

4.1 Merits of the Protocol

- The Protocol is a multilateral environmental agreement with potentially serious implications for global agricultural trade and the delivery of food aid in times of crisis.

- The Protocol can be implemented in a manner that both accomplishes the important goal of biodiversity protection and provides for uninterrupted trade in commodities.

4.2 De-merits of the protocol

- The Protocol only provides broad guidance and there is widespread misunderstanding regarding what the Protocol requires. For instance, it requires documentation for bulk commodity shipments, but it does not require labeling at the consumer level. Further, bulk commodity shipments are not subject to the AIA procedure of the Protocol. The AIA procedure is only required for LMO shipments intended for direct introduction into the environment, such as seeds for planting.

- The Protocol effectively requires agricultural commodity shipments to be accompanied by documentation related to the Living Modified Organisms content but does not provide details on this requirement.

4.3 Suggestions to improve the protocol

- There needs to be more meeting of the parties(MoP), where they seek to provide clarity and guidance for Parties as they seek to comply with their obligations under the protocol. Among the issues to be discussed are information sharing, including the Biosafety Clearinghouse; capacity-building; liability and redress; compliance; and documentation requirements.

- The protocol needs to find ways for Parties and non-Parties alike to adopt practical and effective measures for implementing the Protocol that will meet the environmental protection objectives of the Protocol without disrupting the global grain trade.

- While the protocol adopts a precautionary approach to the research and development of LMOs, this should be limited to the domains of research and development and should not impede the trade of commodities that have been deemed safe under the ambit of the protocol.

- Member nations of the protocol need to expedite the effective implementation of the protocol by clearing all ambiguity and misunderstanding regarding what the protocol requires.

- Further, member nations need to consider the possibility of adding a deterrent clause to the protocol, where if a particular member nation blatantly violates any part of the protocol and further does not provide proper accountability for their actions, they can be imposed with economic and trade sanctions.

5 Role of iGEM as a competition

Given the emphasis iGEM has placed on balancing our wet lab work and human practices work, it would be great if it could extend it a point where participants are made aware of the regulatory framework in their country. This can possibly be done by adding an optional medal criteria where teams are made to reach out to the respective regulatory body(ies) in their country and get their feedback on how they can modify/develop their project so that it complies with the provisions/mandate of the regulatory framework in their nations.

The benefits of this is two-fold, the participants understand the functioning of the regulatory mechanism in their country and are encouraged to view and work on their project from that perspective. Second, the regulatory bodies are made aware of the kind of innovation and research being done in Universities thereby making sure that the regulatory framework is upto speed with the development of science.

Also, given the short time period of an iGEM project , Universities with recurring participation in iGEM need to encourage its students on how they can take their previous years project from research to commercialization.

6.Bibilography

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